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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,886	NILSEN-HAMILTON, MARIT	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) *2 and 11-55* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/30/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1 and 3-18 in the reply filed on 2/3/2006 is acknowledged. The traversal is on the ground(s) that there is no search burden to examine the restricted second targets because each of the second targets share a substantial structural feature in that they each bind to the probe. This is not found persuasive because as detailed in the restriction requirement filed 1/4/2006, each of the second targets do not share a common core structure, each second target is functionally independent and distinct, and each of the second targets do not share a common utility. Furthermore, each of the claimed second targets functions differently when bound to a probe comprising an allosteric regulator and an aptamer. Additionally, a search for an allosteric regulator or an aptamer that binds a specific second target, such as a lipopolysaccharide, will not necessarily reveal art for an aptamer that binds to a different second target, such as a tumor cell.

The requirement is still deemed proper and is therefore made **FINAL**.

Status of the Application

Claims 1 and 3-10 are pending and currently under examination. Claims 11-18 are withdrawn as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**

Claims 1 and 3-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims are drawn to a probe for binding a plurality of targets comprising an allosteric regulator linked to at least one regulated aptamer wherein binding the allosteric regulator with a first target enhances the binding of at least one regulated aptamer to at least one second target, wherein the allosteric regulator comprises a tobramycin aptamer and the regulated aptamer comprises an ATP aptamer, wherein the allosteric regulator is a nucleic acid, wherein the allosteric regulator is an aptamer, wherein the aptamer is capable of binding targets selected from the group as listed in claim 8, wherein the first target is prostate specific antigen and wherein the second target is a lipopolysaccharide.

The specification as filed discloses preparation of an aptamer targeting LPS (Example 1) and a general method of preparing and isolating RNA aptamers using SELEX (Example 2). Further, the specification discloses prophetically how to generate an allosteric aptamer to prostate specific antigen and a regulated aptamer to inulin.

The specification does not provide adequate written description of a probe for binding a plurality of targets comprising an allosteric regulator linked to at least one regulated aptamer wherein binding the allosteric regulator with a first target enhances the binding of a regulated aptamer to a second target. Further, the specification does not provide adequate written description of a probe comprising a tobramycin aptamer and an ATP aptamer wherein binding of a tobramycin aptamer to a target enhances the binding of an ATP aptamer to a second target. The specification does not provide adequate written description of a probe comprising an allosteric regulator that binds to prostate specific antigen wherein binding of a regulated aptamer is enhanced nor does the specification provide adequate written description of a probe comprising any allosteric aptamer that when bound to a target enhances binding of a regulated aptamer to a lipopolysaccharide.

Therefore, in only disclosing an example of a LPS aptamer and a general method for preparing and isolating aptamers, the specification does not provide information on what allosteric regulator directed to a target, namely prostate specific antigen, that when bound to said target would increase the binding of a regulated aptamer to a second target. The specification fails to provide any structure or sequence that would impart the recited activity of an allosteric regulator that is capable of binding to a first target such that enhancement of binding of a regulated aptamer to a second target occurs. Further, the specification does not provide any specific examples or an adequate number of species to represent the claimed genus of allosteric regulators or regulatable aptamers.

The specification has failed to show, for example, any core structure or motif such that a skilled artisan would know that a particular allosteric regulator when bound to a target would have the function of increasing the binding of a regulated aptamer to a second target as required by the claims and further the specification does not provide specific guidance that would allow one the skilled artisan to recognize that Applicant was in possession of the instant invention, commensurate in scope with what is now claimed.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

MPEP 2163 states in part, "An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the

expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that "[w]ithout such disclosure, the claimed methods cannot be said to have been described.")

Thus, the instantly claimed invention cannot be said to have been adequately described in a way that would convey with reasonable clarity to those skilled in the art that, as of the filling date sought, applicant was in possession of the claimed invention because the specification, while providing general information a method of making and isolating aptamers, does not provide any other information or guidance as to what allosteric regulator when linked to a regulated aptamer would increase the binding of the regulated aptamer to second target after binding of the allosteric regulator to a first target.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Soukup et al. (TIBTECH 1999).

The instant claims are drawn to a probe for binding a plurality of targets

comprising an allosteric regulator linked to at least one regulated aptamer wherein binding the allosteric regulator with a first target enhances the binding of at least one regulated aptamer to at least one second target, wherein the allosteric regulator and aptamer are linked in a cis configuration, wherein the binding of the allosteric regulator has affinity to the first target that is greater than the regulated aptamer affinity for the second target, wherein the allosteric regulator is a nucleic acid, wherein the allosteric regulator is an aptamer and wherein the aptamer is capable of binding FMN.

Soukup et al. teach an allosteric aptamer linked to a ribozyme (see Figure 5). The specification defines a regulated aptamer as an aptamer whose activity is enhanced when an allosteric regulator is bound to the allosteric regulator's target (see paragraph 0033) and further defines aptamers as nucleic acids that can be used to inhibit or interfere with the activity of nucleic acids (see paragraph 0037). Soukup et al. teach the FMN molecule binds the allosteric aptamer wherein the binding enhances the activity of the ribozyme for a target sequence (see Figure 5). The term "linked" is not defined in the claims or specification as filed, therefore for prior art purposes, the term "linked" in reference to the allosteric regulator and aptamer is being interpreted to mean the nucleotides are joined together with a chemical bond, i.e. ester bond, that joins nucleotides in a sequence comprising DNA or RNA.

Thus, Soukup et al. anticipates 1, 3, 4 and 6-8 of the instant application.

Claims 1, 3, 4 and 6-7 are rejected under 35 U.S.C. 102(a) as being anticipated by Burke et al. (Biochemistry 2002).

The instant claims are drawn to a probe for binding a plurality of targets comprising an allosteric regulator linked to at least one regulated aptamer wherein binding the allosteric regulator with a first target enhances the binding of at least one regulated aptamer to at least one second target, wherein the allosteric regulator and aptamer are linked in a cis configuration, wherein the binding of the allosteric regulator has affinity to the first target that is greater than the regulated aptamer affinity for the second target, wherein the allosteric regulator is a nucleic acid and wherein the allosteric regulator is an antisense.

Burke et al. teach an allosteric regulator linked to a ribozyme (see Figure 2). The specification defines a regulated aptamer as an aptamer whose activity is enhanced when an allosteric regulator is bound to the allosteric regulator's target (see paragraph 0033) and further defines aptamers as nucleic acids that can be used to inhibit or interfere with the activity of nucleic acids (see paragraph 0037). Burke et al. teach the allosteric regulator binds a first target wherein the binding enhances the activity of the ribozyme for a second target sequence (see page 6590 and Figure 3). The term "linked" is not defined in the claims or specification as filed, therefore for prior art purposes, the term "linked" in reference to the allosteric regulator and aptamer is being interpreted to mean the nucleotides are joined together with a chemical bond, i.e. ester bond, that joins nucleotides in a sequence comprising DNA or RNA

Thus, Burke et al. anticipates 1, 3, 4 and 6-7 of the instant application.

Claims 1, 3, 4 and 6 -7 are rejected under 35 U.S.C. 102(a) as being anticipated by Chinnapen et al. (Biochemistry 2002).

The instant claims are drawn to a probe for binding a plurality of targets comprising an allosteric regulator linked to at least one regulated aptamer wherein binding the allosteric regulator with a first target enhances the binding of at least one regulated aptamer to at least one second target, wherein the allosteric regulator and the aptamer are linked in a cis configuration, wherein the binding of the allosteric regulator has affinity to the first target that is greater than the regulated aptamer affinity for the second target.

Chinnapen et al. teach an aptamer complex comprising a nucleic acid sequence linked to an aptamer (see Figure 2). Chinnapen et al. teach the nucleic acid sequence is an allosteric regulator that binds hemin wherein binding of hemin enhances binding of the aptamer to Cytochrome c (see Figure 8 and page 5209). The term "linked" is not defined in the claims or specification as filed, therefore for prior art purposes, the term "linked" in reference to the allosteric regulator and aptamer is being interpreted to mean the nucleotides are joined together with a chemical bond, i.e. ester bond, that joins nucleotides in a sequence comprising DNA or RNA. Thus, Chinnapen et al. anticipates claims 1, 3, 4 and 6-7 of the instant application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

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